



FluoGuide has submitted a Clinical Trial Application (CTA) to the Danish Medicines Agency to initiate phase II trial with FG001 in head and neck cancer

Copenhagen, Denmark 23 August 2022– FluoGuide A/S (“FluoGuide” or the “Company”) is delighted to announce that the company has submitted a CTA to initiate a phase II trial in head and neck cancer. The clinical trial will be conducted at Rigshospitalet in Denmark.

Following approval from the Danish Medicines Agency, FluoGuide will initiate the phase II trial in collaboration with Department of Otolaryngology, Head & Neck Surgery and Audiology at the University Hospital, Rigshospitalet, in Denmark. Principal investigator is Anders Christensen, MD, Ph.D.

The phase IIa trial is designed to obtain proof-of-concept in head and neck cancer for our uPAR platform technology used to guide surgical removal of cancer. The plan is to enrol up to 16 patients. The primary endpoint is sensitivity defined as the relative number of patients, where FG001 lights up the cancer confirmed by histopathology. FluoGuide expects top line results to be available in 1H 2023. FluoGuide has selected head and neck cancer due to a high unmet need, and evidence of uPAR being overexpressed in these cancers.

Morten Albrechtsen, CEO says” *Following our strong proof-of-concept result of FG001 in high grade glioma, this trial is a continuation of our intention to elucidate the magnitude of commercial potential for FG001 in multiple cancer types”*

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About FluoGuide

FluoGuide’s primary focus is to maximize surgical outcomes in oncology. The Company’s lead product, FG001, is designed to improve surgical precision by illuminating cancer cells intraoperatively. The improved precision enabled by FluoGuide’s products has a dual benefit – it reduces both the frequency of local recurrence post-surgery and lessens surgical sequelae. Ultimately, the improved precision will improve a patient’s chance of achieving a complete cure and will lower system-wide healthcare costs. The Company is has demonstrated efficacy of F001 as well as it to be well tolerated and safe in the ongoing proof-of-concept clinical study (phase I/II) in patients with high grade glioma undergoing surgery. FluoGuide has also started a phase II trial to demonstrate the effect of FG001 in guiding cancer surgery in patients with lung cancer. FluoGuide is listed on Nasdaq First North Sweden under the ticker “FLUO”.

For more information on the Company’s uPAR technology platform and our pipeline please visit our home page www.fluoguide.com

About head and neck cancer

Head and neck cancer includes cancers in the lining of the lips, tongue, mouth, or upper throat. Head and neck cancers are often occurring in close anatomical proximity to small vital structures such as blood vessels supplying the brain and many important nerves. Further, cosmetic considerations are important for most locations of head and neck cancers. Surgical precision is therefore essential for surgical removal of head and neck cancers. Most head and neck cancers arise from squamous cells and are called squamous cell carcinomas.

Worldwide, head and neck cancer accounts for approximately 900,000 cases and over 400,000 deaths annually. In USA and EU head and neck cancer accounts for approximately 66,000 cases annually and 15,000 deaths, and 250,000 cases and 63,500 deaths, respectively. (Source: (1) Global Cancer Observatory. International Agency for Research on Cancer. World Health Organization. Available at: <https://gco.iarc.fr/> (Accessed on June 06, 2021); (2) Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022; (3) CA Cancer J Clin 2022; 72:7. Gatta G, Botta L, Sánchez MJ, et al. Prognoses and improvement for head and neck cancers diagnosed in Europe in early 2000s: The EURO CARE-5 population-based study. Eur J Cancer 2015; 51:2130.)